

Vaccine by Nov. 3? Halted study explains just how unlikely

September 9 2020, by Lauran Neergaard



In this Wednesday, June 24, 2020 file photo, a volunteer receives an injection at the Chris Hani Baragwanath hospital in Soweto, Johannesburg. This is part of Africa's first participation in a COVID-19 vaccine trial developed at the University of Oxford in Britain in conjunction with the pharmaceutical company AstraZeneca. (Siphiwe Sibeko/Pool via AP)

The suspension of a huge COVID-19 vaccine study over an illness in a single participant shows there will be "no compromises" on safety in the race to develop the shot, the chief of the National Institutes of Health told Congress on Wednesday.

AstraZeneca has put on hold studies of its vaccine candidate in the U.S. and other countries while it investigates whether a British volunteer's illness is a side effect or a coincidence.

"This ought to be reassuring," NIH Director Dr. Francis Collins said before a Senate committee. "When we say we are going to focus first on safety and make no compromises, here is Exhibit A of how that is happening in practice."

Scientists have been scrambling to develop a vaccine against the coronavirus since the outbreak began, and the U.S. has launched the world's largest studies—final-stage testing of three leading candidates, with three more trials set to come soon that will each recruit 30,000 test subjects.

Public health experts are worried that President Donald Trump will pressure the Food and Drug Administration to approve a vaccine before it is proven to be safe and effective, a concern senator after senator echoed on Wednesday.

"When it comes to a COVID-19 vaccine, we can't allow President Trump to repeat his alarming pattern of putting politics ahead of science and public health," said Sen. Patty Murray of Washington, the committee's ranking Democrat.



Dr. Francis Collins, Director of the National Institutes of Health, attends a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Greg Nash/Pool via AP)

The U.S. has invested billions of dollars in efforts to quickly develop multiple vaccines against COVID-19. But public fears that a vaccine is unsafe or ineffective could be disastrous, derailing the effort to vaccinate millions of Americans.

Collins said the public needs to understand the process behind telling when any vaccine candidate is ready for widespread use—one that by design is keeping both manufacturers and politicians in the dark until the

evidence gels.

About 150 COVID-19 infections in a study of 30,000 people should be enough to tell if that candidate really is working—and an independent group of experts, not the FDA, gets to do the counting.

WHO MONITORS THE STUDIES?

Every vaccine trial is overseen by a "data and safety monitoring board," or DSMB. These boards include scientists and statisticians who are experts in their fields but have no ties to either the government or the vaccine makers.



This July 18, 2020, file photo, shows the AstraZeneca offices in Cambridge, England. AstraZeneca announced Monday, Aug. 31, its vaccine candidate has entered the final testing stage in the U.S. The company said the study will involve up to 30,000 adults from various racial, ethnic and geographic groups. (AP Photo/Alastair Grant, File)

The top priority: watching for safety concerns, like the one that sparked a DSMB in Britain to pause AstraZeneca's vaccinations and alert its U.S. counterpart.

But this is the group that also will decide when each vaccine is ready to be evaluated by regulators.

In each 30,000-person study, about half the participants are given the real vaccine and half get dummy shots, and neither they nor their doctors know which is which. Only the DSMB has the power to unlock the code of who got which shot and peek at how the volunteers are faring before a study is finished.

The FDA can't even begin to consider approving a vaccine until the DSMB says the data is good enough for that debate, Collins stressed. Once that happens, the FDA has pledged to bring each candidate before a public vaccine advisory committee.



Dr. Francis Collins, Director of the National Institutes of Health, gives an opening statement during a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Greg Nash/Pool via AP)

DOING THE MATH

The FDA already has told manufacturers it won't consider any vaccine that's less than 50% effective.

Say one vaccine trial records that 150 volunteers have gotten sick. The DSMB finds that 100 had received dummy shots and 50 had received the real vaccine. The expert group might decide that's a promising enough

vaccine to stop the study early so that the FDA can debate its merits, even before getting final outcomes from all 30,000 volunteers, said Dr. Larry Corey of the Fred Hutchinson Cancer Research Institute, who is overseeing the U.S. government's vaccine studies.

On the other hand, if equal numbers from the vaccine and placebo groups got infected, the DSMB might declare a vaccine futile, he told The Associated Press. These panels also can calculate infections even before that 150 threshold is met, at set time points in each study.



Sen. Maggie Hassan, D-N.H., listens to Surgeon General Jerome Adams give an opening statement during a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Greg Nash/Pool via AP)

"If your vaccine is at least 50% effective, you're going to know it because you're going to see a big skewing" of infections, NIH's Collins told the Senate's health, education, labor and pensions committee. "You count those events and you know whether it worked or not."

ANSWERS UNLIKELY BEFORE THE U.S. ELECTION

Getting the right math before November, as Trump has promised, is "incredibly unlikely," Corey said.

Collins expressed "cautious optimism" that one of the vaccines being tested will pan out by the end of the year but warned: "Certainly to try to predict whether it happens on a particular week before or after a particular date in early November is well beyond anything that any scientist right now could tell you."

And even if a study has a spate of infections large enough to prove the effectiveness question, the DSMB also must be comfortable that there's enough evidence of safety before opening the books to the FDA. Generally, the FDA is requiring safety data from at least 3,000 people, Surgeon General Jerome Adams told the Senate panel.



In this Aug. 14, 2020, file photo, laboratory technicians work at the mAbxience biopharmaceutical company on an experimental coronavirus vaccine developed by Oxford University and the laboratory AstraZeneca in Garin, Argentina. AstraZeneca announced Monday, Aug. 31, its vaccine candidate has entered the final testing stage in the U.S. (AP Photo/Natacha Pisarenko, File)

This process isn't new—Phase 3 studies of vaccines and therapies are always done this way, though rarely in so bright a spotlight.

SUSPENDING A STUDY NOT THAT RARE

It's not uncommon for pauses in research to investigate whether an unexpected health complaint is really related to a vaccine or not, Collins told senators worried about what the AstraZeneca suspension means for

the nation's year-end goal.

"The reason we're investing not in one but six different vaccines is because of the expectation that they won't all work," Collins said.

AstraZeneca gave no details on the illness, but Collins said it involved a "spinal cord problem." Earlier-stage studies hadn't revealed any serious side effects, but that's a key reason for doing ever-larger phases of research—to widen the search for any reactions.



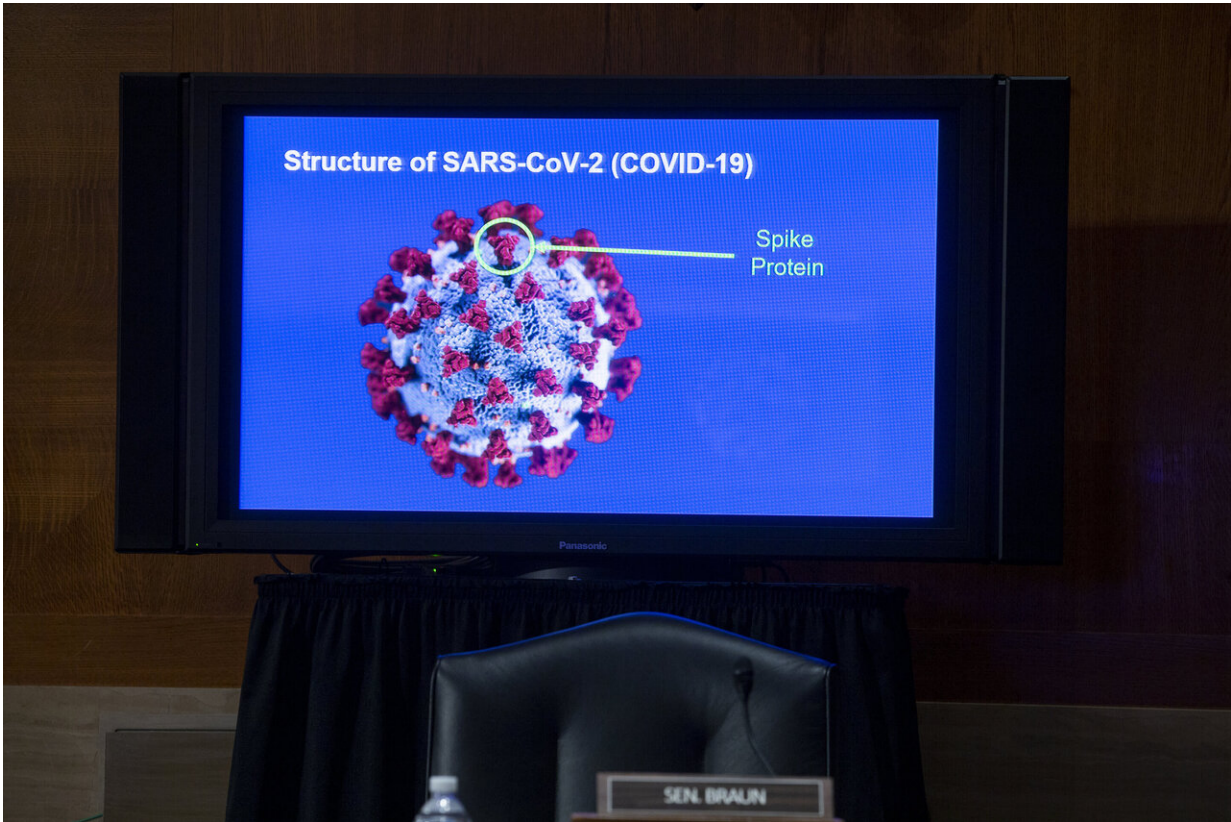
Surgeon General Jerome Adams takes off his face mask as he appears before a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Michael Reynolds/Pool via AP)



Surgeon General Jerome Adams speaks to Dr. Francis Collins, Director of the National Institutes of Health, as they arrive for a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Greg Nash/Pool via AP)



Sen. Patty Murray, D-Wash., gives an opening statement during a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Greg Nash/Pool via AP)



A monitor depicts the structure of SARS-CoV-2 during a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Michael Reynolds/Pool via AP)



Sen. Susan Collins, R-Maine, listens to Surgeon General Jerome Adams give an opening statement during a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Greg Nash/Pool via AP)



Sen. Tim Kaine, D-Va., listens to Surgeon General Jerome Adams give an opening statement during a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Greg Nash/Pool via AP)



Dr. Francis Collins, Director of the National Institutes of Health, arrives for a Senate Health, Education, Labor and Pensions Committee hearing to discuss vaccines and protecting public health during the coronavirus pandemic on Capitol Hill, Wednesday, Sept. 9, 2020, in Washington. (Greg Nash/Pool via AP)

Final testing of two other vaccines is continuing, one created by the NIH and manufactured by Moderna Inc., the other made by Pfizer and Germany's BioNTech. Those two vaccines work differently than AstraZeneca's, which was developed by Oxford University, and the studies already have recruited about two-thirds of the needed volunteers.

Several vaccine candidates made by Chinese companies are in late stages of testing in various countries, but with smaller numbers of volunteers.

Most health authorities are skeptical about a claim of vaccine success by Russia, which has test results from just a few dozen people.

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